



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,188	03/06/2000	Pancras C. Wong	PH-7038	8451

24348 7590 08/29/2002

BRISTOL-MYERS SQUIBB PHARMA COMPANY
PATENT DEPARTMENT
P.O. BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/29/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/519,188

Applicant(s)

WONG, PANCRAS C.

Examiner

Vickie Kim

Art Unit

1614

— The MAILING DATE of this communication appears on the cover sheet with the correspondenc address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 0200 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Application/Control Number: 09/519,188
Art Unit: 1614

DETAILED ACTION

Status of application

1. Claims 8 is canceled upon applicant's request (see paper no 7) and claims 1-7 are now pending.

Election of Species Acknowledged

2. Applicant's election with traverse the species of a combination of aspirin and a Factor Xa inhibitor is acknowledged. During the telephonic interview with Ms. Belfield, applicant withdrew the traverse, see paper no. 13. Claims 1-3 drawn to the use of the elected species in the claimed method have been examined. All remaining claims not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejection is made.

Response to Arguments

2. The declaration under 37 CFR 1.131 filed February 04, 2002 is acknowledged. The prior art 102(e) rejection of claims 1-8 based on Dominguez et al(US patent no. 5,866,191) or Pruitt et al(US patent no: 6,060,491) have been moot in view of the declaration antedating these US patents of the record. New ground of rejection supercedes the rejection made in the previous office action and makes the office action non-final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Application/Control Number: 09/519,188
Art Unit: 1614

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Cariou et al (CA2199642).

Claims 1-3 read on a method of treating thrombosis in a mammal comprising administering a therapeutically effective dose of a combination of a Factor Xa inhibitor and aspirin wherein the dose administered for at least one of a Factor Xa inhibitor and aspirin is a subtherapeutic dose to provide synergistic effect. The subtherapeutic dose in light of specification(see example 1 at page 20, lines 1-14) is exemplified such that the dose of aspirin is 1mg/kg or the dose of factor Xa is 0.1mg/kg. In applicant's own admission, the synergistic effect(see page 18) is most clearly demonstrated at suboptimal concentrations of the compounds.

Cariou et al (CA'642) teach a use of a composition containing aspirin and a selective inhibitor of Factor Xa for treating thromboembolic diseases in a mammal, see abstract and claims 1 and 9-14. Cariou et al further teach an effective dose of the Factor Xa inhibitor or aspirin in said combination composition used in this treatment is 0.1 to 100mg per kilo of bodyweight, respectively. Cariou et al further teach that the treatment is successfully achieved by the combination of aspirin and a Factor Xa inhibitor via two different mechanisms of action(see page 3, lines 20-25). Thus, the claimed subject matter is taught by the cited reference and the recited limitations are met. It is noted that applicant admits that 0.1mg/kg of a factor Xa inhibitor or 1mg/kg of aspirin alone fails to show the therapeutic effectiveness(see at page 20, lines 3-5). Thus, the recited limitation(i.e. synergistic effect) is also inherently possessed when the

successful treatment(i.e. treating thrombosis) is achieved by the patented composition comprising a combination of aspirin and a Factor Xa inhibitor at the suboptimal concentration of each component, for example, 0.1mg/kg of a Factor Xa inhibitor or 0.1-1mg/kg of aspirin, respectively. All the claims are anticipated and not patentably distinct over the prior art of the record.

Conclusion

5. Claims 1-3 are rejected.
6. Claims 4-7 are withdrawn from the consideration as being non-elected. This new ground of rejection is made this office action to be non-final and it supercedes all the rejections made in the previous office action.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
August 13, 2002
Art unit 1614



MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Interview Summary

Application No.

09/519,188

Applicant(s)

WONG, PANCRAS C.

Examiner

Vickie Kim

Art Unit

1614

All participants (applicant, applicant's representative, PTO personnel):

(1) Vickie Kim.

(3) _____

(2) Ms. Belfield.

(4) _____

Date of Interview: 13 August 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
If Yes, brief description: _____

Claim(s) discussed: _____

Identification of prior art discussed: _____

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

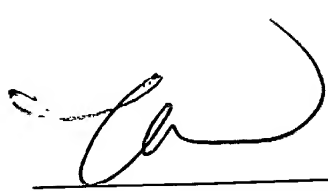
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant request the traverse to the election requirement withdrawn. She admits that the each species is patentably distinct species wherein the election requirement is proper. Thus, the election with traverse found in the applicant's response(see paper no. 12) will be properly replaced with the election without traverse

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required